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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,615	07/27/2006	Myung-Hwa Kim	428.1145	6138
20311	7590	10/20/2010	EXAMINER	
LUCAS & MERCANTI, LLP 475 PARK AVENUE SOUTH 15TH FLOOR NEW YORK, NY 10016				SZNAIDMAN, MARCOS L
ART UNIT		PAPER NUMBER		
1628				
NOTIFICATION DATE		DELIVERY MODE		
10/20/2010		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

info@lmiplaw.com

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/562,615	KIM ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	MARCOS SZNAIDMAN	1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 29 September 2010.

2a) This action is **FINAL**.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 12,13 and 16-21 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 12,13 and 16-21 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application
Paper No(s)/Mail Date _____ .	6) <input type="checkbox"/> Other: _____ .

## **DETAILED ACTION**

This office action is in response to applicant's reply filed on September 29, 2010.

### ***Status of Claims***

Amendment of claims 12 and 13 and cancellation of claims 14 and 15 is acknowledged.

Claims 12-13 and 16-21 are currently pending and are the subject of this office action.

Claims 12-13 and 16-21 are presently under examination.

The examination was expanded in prior office action dated 06/29/10 to the entire genus encompassed by Formula I.

### ***Priority***

The present application is a 371 of PCT/KR04/01518 filed on 06/23/2004, and claims priority to foreign Application: REPUBLIC OF KOREA 10-2003-00415467 filed on 06/25/2003.

### ***Rejections and/or Objections and Response to Arguments***

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated (Maintained Rejections and/or Objections) or newly applied (New Rejections and/or Objections, Necessitated by Amendment or New Rejections and/or Objections not

Necessitated by Amendment). They constitute the complete set presently being applied to the instant application.

***Claim Rejections - 35 USC § 112 (New Rejection not Necessitated by Amendment)***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 17 and 20-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17 recites the following compounds: 19, and 29-32. There is insufficient antecedent basis for these compounds in the claim.

Compound 19 has an extra  $-\text{CH}_2\text{-O-NO}_2$  group in the aromatic ring that apparently does not fit the limitations of R6 in claim 12.

Compounds 29-32 have ester groups as substituents in the aromatic ring, none of which satisfies the limitations of R6 or  $-(\text{CH}_2)_n\text{R}_7$ .

In summary none of the above compounds seem to be encompassed by the general formula I of claim 12.

***Claim Rejections - 35 USC § 103 (New Rejection not Necessitated by Amendment)***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

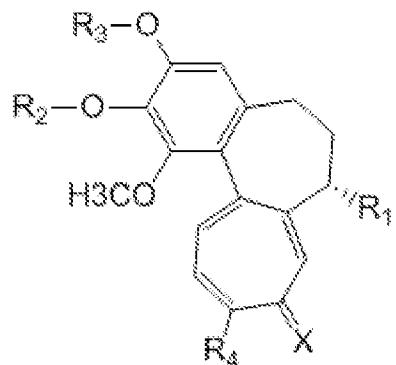
The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 12-13 and 16-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et. al. (WO 02/100824) in view of Patani et. al. (Chem. Rev. (1996) 96:3147-3176).

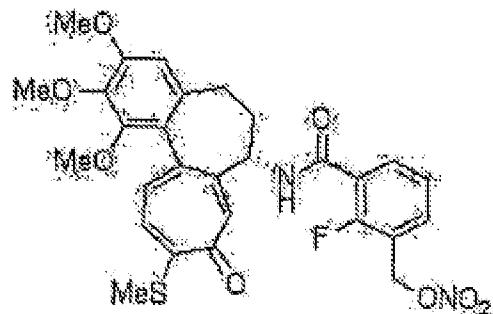
Claims 12-13 and 16-17 recite a tricyclic derivative represented by the following Formula I or pharmaceutically acceptable salts thereof:



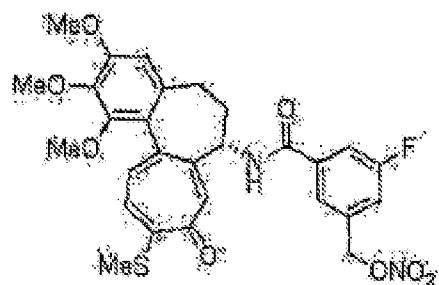
Formula I

More specifically claim 17 recites the following compounds:

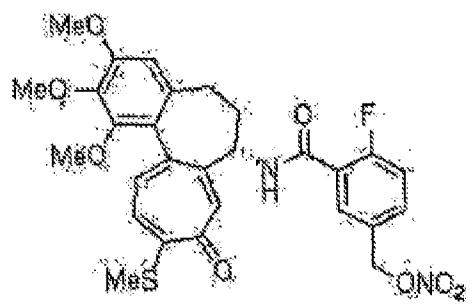
Compound 10:



Compound 12:

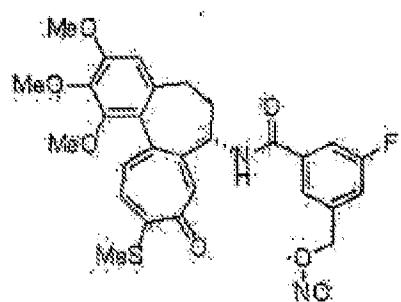


Compound 17:

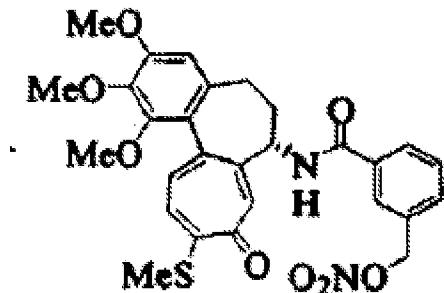


and

Compound 37:



For claims 12-13 and 16-21, Kim teaches the following compound:



(see example 12 on page 28, from now on compound

A)

Kim does not teach the above instant compounds: 10, 12, 17 and 37. However, compound A differs from the instant compounds in the presence of a Hydrogen atom instead of Fluorine atom in the aromatic ring. Patani teaches that the substitution of Hydrogen by Fluorine is one of the most commonly employed monovalent isosteric replacements (see page 3149, left column under 1. Fluorine vs. Hydrogen Replacements). Further in Figure 2 on the same page they give an example wherein replacing Hydrogen with Fluorine in an aromatic ring maintains or improves the pharmacological properties of the compounds. In summary, substituting Hydrogen by Fluorine is routine practice in the pharmaceutical art, and should not alter the biological/pharmaceutical properties.

Further, MPEP 2144, Section III states: prior art structures do not have to be true homologs or isomers to render structurally similar compounds *prima facie* obvious. *In re Payne*, 606 F.2d 303, 203 USPQ 245 (CCPA 1979) (Claimed and prior art compounds were both directed to heterocyclic carbamoyloximino compounds having pesticidal activity. The only structural difference between the claimed and prior art was

that the ring structures of the claimed compounds had two carbon atoms between two sulfur atoms, whereas the prior art ring structures had either one or three carbon atoms between two sulfur atoms. The court held that although the prior art compounds were not true homologs or isomers of the claimed compounds, the similarity between the chemical structures and properties is sufficiently close that one of ordinary skill in the art would have been motivated to make the claimed compounds in searching for new pesticides). In *re Gyurik*, 201 USPQ 552, 596 F2d 1012 on page 557 states: “In obviousness rejections based on close similarity in chemical structure, the necessary motivation to make a claimed compound, and thus the *prima facie* case of obviousness, rises from the expectation that compounds similar in structure will have similar properties.” In this case it is expected, as discussed above, that compounds differing only by the presence or absence of Fluorine in the aromatic ring, would have similar chemical, physical and biochemical properties as discussed above.

At the time of the invention, it would have been *prima facie* obvious for a person of ordinary skill in the art to replace any Hydrogen of the aromatic ring of compound A with a Fluorine in order to obtain either compound: 10, 12, 17 or 37, and expect these compounds to have the same biological/pharmaceutical properties, since the prior art teaches replacing Hydrogen with Fluorine is routine practice in the pharmaceutical art, in order to obtain molecules with similar or better pharmaceutical properties, thus resulting in the practice of claims 12-13 and 16-17 with a reasonable expectation of success.

For claims 18-21, Kim further teaches that the compounds of the invention can be used as pharmaceutical compositions that are effective as anticancer, antiproliferation and immunosuppressive agents (see technical field on page 1). The pharmaceutical composition contains common excipients (see page 19).

At the time of the invention, it would have been *prima facie* obvious for a person of ordinary skill in the art to further make a pharmaceutical composition of the above compounds using common excipients as suggested by Kim, in order to obtain a better way of administering the drug, thus resulting in the practice of claims 18-21 with a reasonable expectation of success.

### ***Double Patenting (New Rejection not Necessitated by Amendment)***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 12-13 and 16-17 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 7,119,229 in view of Patani et. al. (Chem. Rev. (1996) 96:3147-3176).

Claims 1-5 teach similar compounds and pharmaceutical compositions as claimed in the instant application. The prior art compounds only differ in the absence of an halogen (i.e. F, Cl, Br or I) in the aromatic ring. However, Patani teaches that the substitution of Hydrogen by Fluorine is one of the most commonly employed monovalent isosteric replacements (see page 3149, left column under 1. Fluorine vs. Hydrogen Replacements). Further in Figure 2 on the same page they give an example wherein replacing Hydrogen with Fluorine in an aromatic ring maintains or improves the pharmacological properties of the compounds. In summary, substituting Hydrogen by Fluorine is routine practice in the pharmaceutical art, and should not alter the biological/pharmaceutical properties (see also above 103 rejection).

At the time of the invention, it would have been *prima facie* obvious for a person of ordinary skill in the art to replace any Hydrogen of the aromatic ring of compound A with a Fluorine in order to obtain the instant claimed compounds, and expect these compounds to have the same biological/pharmaceutical properties, since the prior art teaches replacing Hydrogen with Fluorine is routine practice in the pharmaceutical art, in order to obtain molecules with similar or better pharmaceutical properties, thus resulting in the practice of claims 12-13 and 16-21 with a reasonable expectation of success.

Claims 12-13 and 16-21 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 7,622,612. Although the conflicting claims are not identical, they are not patentably distinct from each other because many, but not all, of the compounds of claims 1-4 of the US Patent are the same as the instantly disclosed compounds.

***Withdrawn Rejections and/or Objections***

***Claims rejected under 35 USC 112, first paragraph (scope of enablement).***

Due to applicant's amendment of the claims, the scope of enablement rejection is now moot.

Rejection under 35 USC 112, first paragraph (scope of enablement) is withdrawn.

***Conclusion***

No claims are allowed.

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARCOS SZNAIDMAN whose telephone number is (571)270-3498. The examiner can normally be reached on Monday through Thursday 8 AM to 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on 571 272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MARCOS SZNAIDMAN/  
Examiner, Art Unit 1628  
October 13, 2010.